General Responses to EPA's Directive Comments on the Baseline Human Health Risk Assessment

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Risk Management Recommendations	General	For the record, the LWG's position is that no risk management decisions were made in the draft BHHRA and that EPA guidance was followed in providing appropriate risk characterization. As discussed in the September 9th meeting, risk management recommendations for human health will be presented in a document separate from the revised BHHRA. The risk management recommendations would include information such as the following: • Uncertainty discussion (magnitude of uncertainty and considerations on overall risks) beyond that presented in the BHHRA • Support for the selection of certain chemicals for focus in the FS (e.g., cPAHs for direct contact with sediment) • Information about how PRGs should be applied based on human exposures (e.g., clam consumption PRGs should only be applied in areas where harvest could occur) • Whether a sediment-tissue relationship exists and the strength of that relationship Based upon the above information, the document will identify those chemicals recommended for consideration as chemicals of concern (COCs) in the FS.
Use of COCs in the FS and Beyond	105, 191	The LWG believes that chemicals that exceed screening levels but that have not been further evaluated through risk characterization should be considered chemicals of potential concern (COPCs) and not chemicals of concern (COCs). As discussed during the September 9th meeting, chemicals that are evaluated in the revised BHHRA that exceed screening levels will be designated COPCs. COPCs will be carried forward into risk characterization, which will identify those chemicals resulting in

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		cancer risks greater than 10-6 or hazard quotients greater than 1. Those chemicals will be considered in the risk management recommendations, which will recommend the chemicals to be considered COCs in the FS. Sediment PRGs will be developed for COCs, so if a PRG cannot be developed (e.g., due to a lack of sediment-tissue relationship), the chemical will not be recommended for consideration as a COC.
ARAR Evaluation in the BHHRA	26, 105, 171, 191	The LWG believes that it is not consistent with guidance to include an ARAR evaluation in the risk assessment. In addition, EPA's directed changes are not consistent with an ARAR evaluation as RSLs are not ARARs and neither the NRWQC nor the Oregon WQS are currently based on 142 g/day. The BHHRA did, however, evaluate fish consumption scenarios that assumed ingestion rates of 142 and 175 g/day and also evaluated a domestic water use scenario using untreated surface water data for transect and vertically integrated sample locations pursuant to EPA direction. As discussed at the August 20th and September 9th meetings, the revised BHHRA will not include an ARAR evaluation. Surface water and transition zone water (TZW) will be included in a screening evaluation consistent with prior agreements with EPA. The screening evaluation will compare detected concentrations in surface water with NRWQC, NRWQC divided by 10 (to represent an ingestion rate of 175 g/day), MCLs, non-zero MCLGs, and RSLs; and detected concentrations in TZW with NRWQC, MCLs, non-zero MCLGs, and RSLs. Chemicals that exceed the screening criteria will be identified as COPCs in a table, separate from Table 8-1, in the revised BHHRA and will be carried forward into the FS for further evaluation related to contaminant mobility. An ARAR evaluation will be included in the FS.
Risk Driver Section in the BHHRA	General 8, 26, 191	The LWG believes the use of the term "risk driver" and the discussion

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		in Section 8.2 of the draft BHHRA is consistent with guidance. RAGS Part A Section 8.6.1 states that the summary of risk information should include discussion of: "*the major factors driving the site risks (e.g., substances, pathways, and pathway combinations).…confidence that the key site-related contaminants were identified and discussion of contaminant concentrations relative to background ranges.…and level of confidence in the exposure estimates for key exposure pathways and related exposure parameter assumptions*". As discussed at the August 20th and September 9th meetings, Section 8.2 will remain in the revised BHHRA, but the term "Risk Driver" will not be used throughout the revised BHHRA. Instead, terms such as "primary contributor to risk" will be used. Section 8.2 will discuss the relative magnitude of risks associated with the various chemicals and exposure pathways evaluated in the BHHRA.
Directed Changes to Text		
Deletion of Factual Statements and Comments on Remedy	26, 63, 128, 148, 149, 151	The LWG disagrees with EPA's directed changes requiring the removal of factual information from the draft BHHRA. The LWG believes that the addition of statements asserting a need for remediation or goals of remediation in the BHHRA is not consistent with guidance. As discussed at the August 20th and September 9th meetings, factual (i.e., objective) language can remain in the revised BHHRA. Judgmental language (both that in the draft BHHRA and that directed by EPA) will not be included in the revised BHHRA. The need for remediation or goals of remediation will not be discussed in the revised BHHRA. Discussion of remedial goals will be included in the FS consistent with the RAOs.
Deletion of EPA Direction	14, 26, 30, 125	The LWG disagrees with EPA's directed changes requiring the deletion of references to prior EPA direction from the draft BHHRA.

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		As discussed at the August 20th and September 9th meetings, language stating that evaluations were done at the direction of EPA can remain in the revised BHHRA. Language implying opinion or judgment about the prudence of that direction will be removed.
Description of Drinking Water Scenario	General 6, 12, 36, 41,43, 44, 48, 56, 68, 85, 128, 132, 136, 173	The LWG believes that the drinking water scenario was described in the draft BHHRA consistent with RAGS A, and the drinking water scenario was quantitatively evaluated using transect and vertically integrated surface water samples per prior direction from EPA. The LWG does not believe it is appropriate to discuss the need to remediate a resource or ARAR issues in a risk assessment. The LWG also believes "hypothetical" accurately describes the scenario that untreated water would be used for domestic purposes, as evaluated in the surface water drinking scenario. Under OAR 340-041-0340, Table 340A, domestic water supply is a designated beneficial use of the Willamette River, but only with adequate pretreatment. As discussed at the August 20th and September 9th meetings, the term "hypothetical" can be used when describing the use of the Lower Willamette River (LWR) as a domestic water source, as long as factual information is provided to support that characterization. Language regarding the designated beneficial use of the LWR and the need to protect the resource will be included in the revised BHHRA. Language regarding the need to remediate the resource will not be included. The following language is an example of how the scenario will be described in the revised BHHRA: "*Even though no current or future uses of the LWR within Portland Harbor as a domestic water source have been identified, as discussed above under OAR 340-041-0340 Table 340A, domestic water supply is a designated beneficial use of the Willamette River, with adequate pretreatment. Because the Willamette River is capable of serving as a potential drinking water source, the expectation is that this resource*

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		will be protected to achieve such use with adequate pretreatment." Per recent EPA direction, the drinking water scenario will be quantitatively evaluated in the revised BHHRA using the transect and vertically integrated surface water samples and the averaged concentrations of near-bottom and near-surface surface water data where both samples were collected. The full surface water data set will be evaluated separately in the screening evaluation presented in Section 6.
Characterization of Ingestion Rates	General 1, 14, 49, 63, 64, 93, 94, 98, 101, 138, 140	The LWG recognizes that the ingestion rates from the USDA CSFII Study are for both consumers and non-consumers; however, the rates used in the draft BHHRA are equal to the 90th and 99th percentiles, which are considered upper-bound exposures per RAGS A: "If statistical data are available for a contact rate, use the 95th percentile value for this variable. (In this case and throughout this chapter, the 90th percentile value can be used if the 95th percentile value is not available.)" Furthermore, the draft BHHRA did not consider the fraction of fish consumed from the site, did not account for reductions due to preparation and/or cooking methods, and assumed consumption of resident fish only (i.e., no anadromous fish such as salmon). Therefore, applying the 90th and 99th percentile ingestion rates for all fish and shellfish consumption combined in a national diet study to consumption of resident fish only exclusively from Portland Harbor is an uncertainty, as discussed in the draft BHHRA. As discussed at the September 9th meeting, ingestion rates will be presented in the revised BHHRA as the numeric rates (i.e., grams per day or meals per month) and the source of the rates will be presented, consistent with the text in the Programmatic Work Plan. Characterization or descriptors of the ingestion rate (e.g., "low", "high") will not be included in the revised BHHRA.
Deletion of Language	General 4, 75, 83, 96, 102, 170,	The LWG believes that the combination of multiple conservative

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Regarding Compounding of Conservative Assumptions	174, 193, 198	assumptions does result in risks for certain scenarios that are greater than those that are "reasonably anticipated to occur at a site", which is the definition of reasonable maximum (RAGS A, Page 6-4). For example, it is not anticipated that an individual would eat 19 meals of whole body carp caught within the Study Area that had no preparation or cooking every single month for 30 years. However, the LWG recognizes that the concept of reasonable maximum exposure (RME) involves the use of professional judgment. Per RAGS Volume 3 Part A, "*the 90th to 99.9th percentiles of the risk distribution are collectively referred to as the* ***recommended RME range***", and the risk manager chooses the specific percentile to represent the RME individual. As discussed at the September 9th meeting, language regarding the compounding of conservative assumptions will not be included in the revised BHHRA. Factual information about the range of the exposure assumptions and how the combination of those assumptions may fall within the RME range of 90th to 99.9th percentiles can be included in the revised BHHRA.
Clam Consumption Scenario	12, 96, 126, 147	The LWG believes the draft BHHRA accurately describes the shellfish consumption scenario because there is no documentation that shellfish consumption actually occurs on an *ongoing* basis within the Study Area (italics indicate emphasis added). ODFW provided the crayfish landing reports for 2005 through 2007, and there were no reported commercial crayfish landings for the Willamette River in Multnomah County during this time. As stated by EPA, an average of 4,300 lbs of crayfish was commercially harvested from the portion of the Willamette River within Multnomah County in each of the 5 years from 1997 to 2001. The draft BHHRA included an evaluation of crayfish consumption consistent with prior EPA direction. The Linnton Community Center study may support the assumption that transients currently consume bivalves. However, there are significant

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		concerns with the validity of that survey, and the exposure duration for transients is much less than that used in the draft BHHRA to evaluate clam consumption. In addition, there is no empirical basis for the assumption that bivalve biomass would increase in the future without additional evaluation of future conditions, including habitat and accessibility. As discussed at the August 20th and September 9th meetings, the clam consumption scenario can be factually discussed in the revised BHHRA. Language regarding the evaluation of shellfish consumption at the direction of EPA and that the harvest and possession of Asian clams is illegal can remain in the revised BHHRA. Information from the Linnton study will be cited as such. Language implying opinion or judgment about the clam consumption scenario will not be included in the revised BHHRA.
Regional Tissue Concentrations	26, 193	The LWG believes that the regional tissue concentrations provide important context to the public in understanding the fish consumption risk results. As discussed at the September 9th meeting, regional tissue data can be included in the RI. Information included in the RI can be included in the revised BHHRA in a factual manner but not to qualify risks for the Site. If regional tissue data are included, the following context needs to be provided: concentrations are higher at the Site than in the regional tissue, the sources of the regional tissue concentrations are unknown, regional efforts are underway to reduce concentrations, and additional information about the studies (e.g., fish species, size of fish).
Other	108, 109, 133, 141, 142, 150, 162	The LWG believes that the language in the draft BHHRA is accurate and consistent with risk assessment guidance and disagrees that the changes directed in these comments are needed. As discussed at the September 9th meeting, the BHHRA will be

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		revised per these directed changes.